

## Effects of wear time recording on the patient's compliance

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### ABSTRACT

**Objective:** To assess the effect of wear-time recording on subjective and objective wear time.

**Materials and Methods:** This study retrospectively examined a group of 18 patients and a control group of 14 patients at four appointments over 168 days. The patients were treated with removable appliances with embedded TheraMon-microsensors to be worn for 15 hours per day. The study group was not told about the microsensor until the first appointment after fitting of the appliance. At each appointment patients were asked about their subjective wear time and afterward were told about the objective wear time. The existence of the microsensor was revealed to the control group when the appliance was fitted. Objective wear time was also announced at every appointment.

**Results:** Mean wear times did not significantly differ between groups at any appointment or regarding overall wear time. Highly significant differences between subjective and objective wear time were found when patients did not know that their wear time had been monitored.

**Conclusion:** Mean wear times assessed in this study concur with data of previous studies. Patients tend to overestimate their wear times but become more realistic once they know wear time is being monitored. Objective measurement of wear time allows a more realistic view of compliance by patient and orthodontist. Knowing that wear time is recorded does not necessarily increase the amount of time removable appliances are worn by the patient. (*Angle Orthod.* 2013;83:1002–1008.)

**KEY WORDS:** Wear time; Compliance; Removable appliances

### INTRODUCTION

Compliance describes the way patients follow the orders given by the orthodontist.<sup>1</sup> It is regarded as a key factor for treatment success, especially when using removable orthodontic devices. Compliance depends on such factors as regimen and comfort, patient's personality, and parental guidance.<sup>2</sup> In particular, patients with poor cooperation tend to overestimate their wear times.<sup>3</sup>

Fifty-eight percent of the girls accept the requested wear times, whereas only 28% of the boys do so. The willingness to wear removable appliances rises when an improvement in appearance is promised to the patients.<sup>4</sup> To achieve a satisfactory result or to retain a result, the removable appliances have to be worn for a certain number of hours per day. The minimum wear time necessary to achieve a treatment goal is estimated to be 12.8 hours per day for functional appliances and 13.9 hours per day for active plates.<sup>5</sup> Previous studies have shown that a patient's wear time reaches approximately 50–60% of the time prescribed by the orthodontist an average 7.65 hours per day.<sup>6</sup>

Age, gender, type of retainer, and time since removal of the fixed appliance were identified as significant factors associated with the patient's compliance in the retention phase.<sup>7</sup> Other studies report no influence of age, sex, and type of retainer on patients' compliance.<sup>8</sup> Some studies suggest that nighttime-only/part-time-only removable retainer wear may be sufficient.<sup>9,10</sup> Others advise the removable retainer to be worn nearly 24 hours a day for the first 6 months after debonding, followed by 12 to 14 hours daily.<sup>11</sup>

Objective measurement of wear time has been demanded in orthodontics for a long time. In cases of

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**Table 1.** Overview of the Study Group and Control Group Regarding Number, Age (Years), Gender, and Appliances Used

|                        | Study Group   | Control Group | Total         |
|------------------------|---------------|---------------|---------------|
| No.                    | 18            | 14            | 32            |
| Age                    | 14.11 (±4.17) | 11.02 (±2.07) | 12.76 (±3.70) |
| Male                   | 8 (44.4%)     | 9 (64.3%)     | 17            |
| Female                 | 10 (55.6%)    | 5 (35.7%)     | 15            |
| Appliances used        |               |               |               |
| Activator              | 5             | 7             | 12            |
| Bite-jumping appliance | 9             | 3             | 12            |
| Plates                 | 4             | 4             | 8             |

failure or stagnating treatment it helps find possible explanations.<sup>1</sup> Wear-time measurement might affect the relationship between the patient and the orthodontist because it interferes in patient privacy in a negative way.<sup>1</sup>

Studies show that patients sometimes are not very honest or unrealistic concerning their reported wear times. On average, these patients wear their appliance about 12.4 hours less than the more honest patients.<sup>12</sup> Therefore, different devices have been introduced to measure the objective wear time of removable appliances.<sup>13–16</sup> Most of these devices consist of a microsensor that is embedded in the appliances. Current versions of these devices deliver a clinically sufficient accuracy.<sup>15</sup> This permits an objective assessment of wear time.

Patients aware of the fact that wear time is monitored wear their appliances significantly more often than patients unaware of this.<sup>12</sup> Until now, however, no studies have assessed how wear time and the subjective assessment of wear time change when monitoring is revealed to patients.

**MATERIALS AND METHODS**

**Patients and Appliances**

The chairman of the ethical committee of the university hospital of Duesseldorf approved this retrospective investigation. A sample size of 37 patients consecutively treated at the department was investigated. No selection was performed. Five patients dropped out (13.5%) because they missed at least one appointment, resulting in a total of 32 patients: 18 patients in the study group and 14 forming the control group (Table 1). The study group comprised 10 female and 8 male patients. Their ages ranged between 6.42 and 21.25 years at the beginning of treatment with removable appliances/retainers. Eight patients in the study group wore removable retainers. The control group comprised 5 girls and 9 boys between 8.08 and 14.83 years old (Table 1). All patients were monitored for half a year with appointments every 6 weeks (T1–T4). This resulted in wear-time data for each patient for a total of 168 days.

A TheraMon-microsensor (Handelsagentur Gschladt, Hargelsberg, Austria) was embedded into each appliance by the technician and activated according to the manufacturer’s instructions. Removable appliances, bite-jumping appliances, activators, and plates were used. An overview of the appliances’ distribution is given in Table 1.

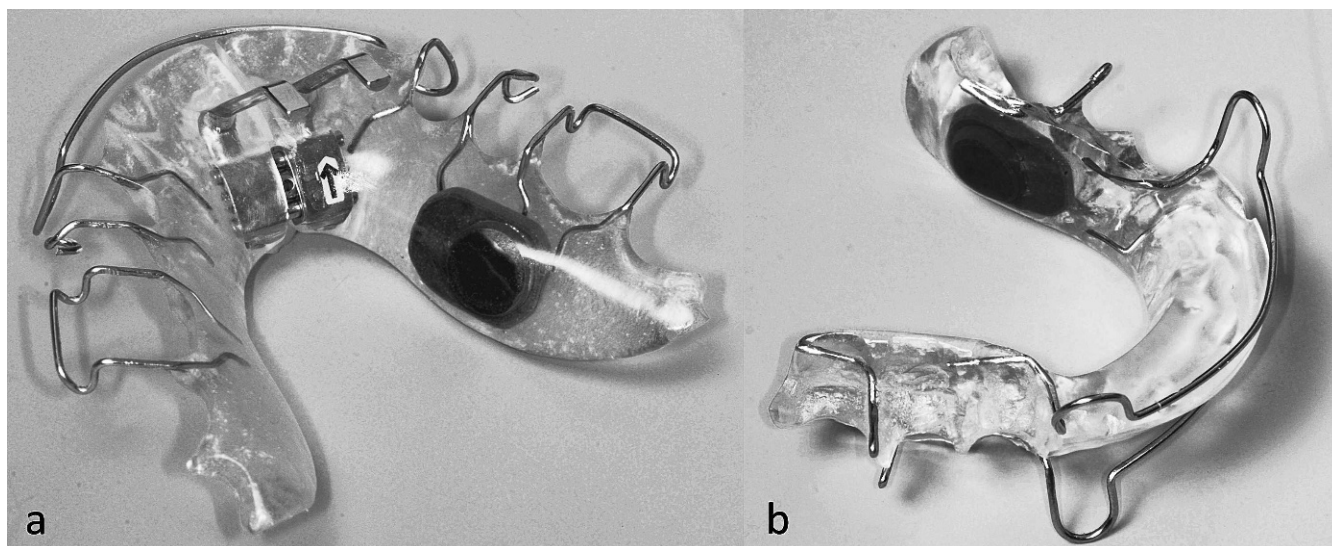
Exclusion criteria for this study were patients with syndromes, clefts, or other systemic diseases as well as previous use of removable appliances in therapy. Inclusion criteria were the necessity for a removable functional appliance or the need for a removable retainer after removal of the fixed orthodontic appliance and the patient’s showing up for each appointment during 6 months. None of the patients had worn removable appliances before. Success of therapy was not an inclusion criterion.

**The Microsensor**

The TheraMon-sensor used in this study is a relatively small (12.8 × 8.7 × 4.2 mm) device covered by polyurethane.<sup>17</sup> It uses an application-specific integrated circuit with 16 kilobyte internal Electronically Erasable Programmable Read-Only Memory (EEPROM-memory). The sensor is embedded into the removable appliance by the technician (Figure 1). It measures the temperature in the mouth with an accuracy of ±0.1°Celsius for up to 18 months. The temperature is recorded every 15 minutes.

The data are transmitted to a computer using a wireless connection between the removable appliance and a readout station coupled by a universal serial bus connection. The TheraMon-software reads and interprets the data. A diagram with the relevant information is generated (Figure 2).

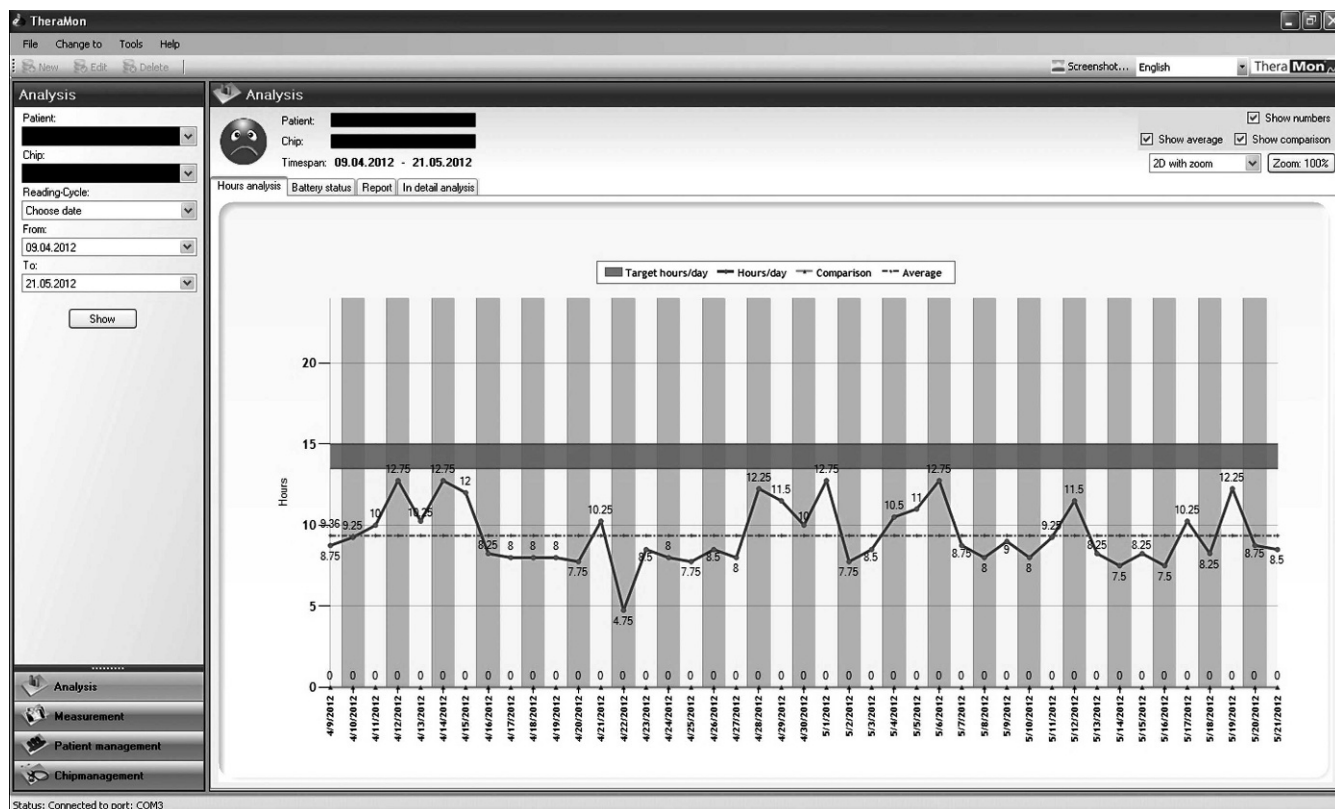
Patient deception, for example, using a water bath with temperature control or putting the appliance on a heater, can be revealed by viewing the temperature curves in detail. Each heating device has a specific temperature profile showing a different temperature curve other than what is usually expected in the oral cavity (Figure 3).



**Figure 1.** Removable appliances, (a) bite-jumping appliance and (b) activator, with embedded TheraMon-microsensors.

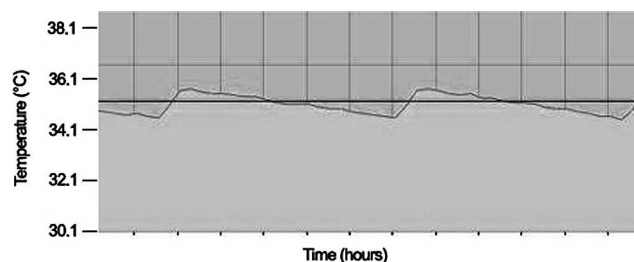
The clinically sufficient accuracy of the TheraMon-sensor has already been investigated in vitro.<sup>15</sup> To assess the accuracy of the TheraMon-sensor in vivo before this study, the removable appliance of a postgraduate student in our department was equipped

with a microsensor. Each day the exact time when the appliance was inserted and removed was recorded over a period of 2 weeks. The data were evaluated, revealing a discrepancy of 7.92 minutes per day between the wear time recorded by the microsensor



**Figure 2.** TheraMon-microsensor software showing a diagram of the daily wear times over a 6-week span. Mean wear time (9.36 hours per day) is clarified by the dotted line, and the blue bar signifies the prescription of 15 hours per day. The unit of the x-axis is days.





**Figure 3.** Detail view of a temperature curve showing the typical temperature profile caused by a heating device.

and the wear time stated by the postgraduate student. This accuracy seems to be acceptable given the fact that the temperature is recorded only every quarter of an hour. Thus, the TheraMon-sensor can be regarded as a sufficiently accurate device for this study.

### Study Protocol

When the removable appliance was fitted, each patient was instructed to wear the appliance for 15 hours per day, matching the common recommendation.<sup>5</sup> Also, the patients with removable retainers were told to wear it for 15 hours per day, corresponding to the references in the literature ranging between recommendations for nighttime-only use and initial wear for nearly 24 hours a day.<sup>9-11</sup> Patients were instructed how to wear and clean the appliance and motivated intensively.

At the appointment when the removable appliance was fitted (T0), the patients in the study group were not told about the microsensor. The patients were only introduced to the microsensor at T1. At T1, T2, T3, and T4 the patient and/or a parent were asked about their estimation of wear time. Investigators made sure to ask the patient in detail and to draw his own conclusion from the information given by the patient and/or parent as requested by Sahm et al.<sup>3</sup> to maximize accuracy. Afterward, the patient was told about the objective wear time measured by the TheraMon-system and motivated if necessary. This protocol allowed investigators to assess the change in discrepancies between subjective and objective wear time between the appointments. The control group was told about the existence of the microsensor at T0 and told about their objective wear time at T1, T2, T3, and T4.

### Statistics

Statistics was performed using SPSS version 19 (IBM, Armonk, NY). All data were tested for normal distribution using the Shapiro-Wilk test.

Distribution of age among the groups was examined using unpaired *t*-test. Gender discrepancies between groups were assessed using the  $\chi^2$  test. Regarding

mean overall wear time, data were examined for significant differences between types of appliances and genders using unpaired *t*-test.

Objective wear times of the study group and the control group at each appointment were tested for significant differences using unpaired *t*-test and Mann-Whitney U-test. To assess significant differences between subjective and objective wear times in the study group, data were compared using a paired *t*-test and Wilcoxon test.

To describe differences between the objective wear times in the control group, analysis of variance was applied. As a further test, the Friedman test was used to analyze significant differences between the subjective and objective wear times of the study group as well as differences at each appointment comparing that appointment to all the others using the Wilcoxon test. For all tests *P* levels < .05 were regarded as significant and *P* levels < .01 as highly significant.

### RESULTS

Regarding age, the two groups showed no significant differences (*P* = .11). Regarding distribution of genders, no significant differences could be determined between the study and the control group (*P* = .272). No statistically significant differences between genders could be found in the study group concerning overall wear time (*P* = .854).

To examine whether any discrepancies between retention appliances and active appliances were present, overall wear-time data for the study group was used. The distribution amounted to 8 removable retainers and 10 active appliances, which showed no significant differences regarding overall wear time (*P* = .636).

Mean wear time in the study group was 8.1 hours per day  $\pm 2.3$ . In the control group a mean wear time of 7.5 hours per day  $\pm 1.8$  was found. Mean wear times at each appointment for both groups are shown in Table 2.

No significant differences of wear time could be found between the study group and the control group regarding mean wear time over 168 days and for T1, T2, T3, and T4 (Table 2). No significant differences between objective wear times could be found at any point during the study in the control group (*P* = .337) or the study group (*P* = .769). However, significant differences between the different subjective wear times in the study group could be detected (*P* = .008). Only the subjective wear time at T1 showed significant differences compared with all other appointments (Table 3). Concerning subjective and objective wear time, in the study group highly significant discrepancies (*P* = .001) could be found for T1, when

**Table 2.** Comparison Between Study Group and Control Group Regarding Mean Measured Wear Time (Hours per Day) for Each Appointment (T1, T2, T3, T4) and Overall Wear Time (T1–T4)

| Group         | T1                 | T2                 | T3                 | T4                 | T1–T4              |
|---------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| Study group   | 8.1 ( $\pm 3.05$ ) | 8.4 ( $\pm 2.78$ ) | 8.2 ( $\pm 2.36$ ) | 8.1 ( $\pm 2.19$ ) | 8.1 ( $\pm 2.29$ ) |
| Control group | 6.7 ( $\pm 2.06$ ) | 7.4 ( $\pm 2.47$ ) | 7.9 ( $\pm 2.17$ ) | 8.1 ( $\pm 1.72$ ) | 7.5 ( $\pm 1.81$ ) |
| <i>P</i>      | .167               | .287               | .671               | .274               | .430               |

patients did not know about the sensor. Data for T2–T4 showed no significant differences between subjective and objective wear time (Table 4).

In the study group, the differences between objective and subjective ([Objective wear time] – [Subjective wear time]) time also showed highly significant differences ( $P = .003$ ). Comparing the differences of each appointment to the others, only the difference between objective and subjective wear time at T1 and all others reached the level of significance. All other combinations were not statistically significant (Table 5).

## DISCUSSION

The clinically sufficient accuracy of the TheraMon-microsensor in vitro has already been investigated in another study;<sup>15</sup> thus, the accuracy in vivo was investigated before this study. For this purpose, a postgraduate student was recruited to obtain a high reliability of the recorded data.

Regarding objective mean wear times, this study supports findings in the literature<sup>6</sup> where an average wear time of 7.7 hours is described. In this study, combining the two groups, an average wear time of 7.9 hours per day  $\pm 2.1$  could be detected. This matches the findings that patients wear their removable appliances approximately 50–60% of the wear time prescribed by the orthodontist.<sup>6</sup>

The demanded wear time in this study was adapted to the amount of 15 hours per day as advised in literature.<sup>5,9–11</sup> The period of time of 6 weeks between appointments was adapted to the interval usually prescribed at our department.

Each patient in the study group was asked for the subjective amount of time the appliance had been worn per day at each appointment. The patient was asked in detail and the conclusion was drawn based on the information the patient and/or a parent provided as requested in literature.<sup>3</sup>

**Table 3.** Comparison of the Subjective Wear Times of the Study Group at Each Appointment (T1, T2, T3, T4) to All Others; Significant Values ( $P < .05$ ) Appear in Italics

|    | T1   | T2   | T3   | T4 |
|----|------|------|------|----|
| T1 |      |      |      |    |
| T2 | .022 |      |      |    |
| T3 | .011 | .519 |      |    |
| T4 | .005 | .450 | .442 |    |

This procedure was chosen because it is known that estimates regarding wear time differ significantly between orthodontists, parents, and patients,<sup>18</sup> and patients tend to overestimate their wear times.<sup>3</sup> This study shows that the differences between objective and subjective wear time decreases significantly after patients are aware of the existence of wear-time recording. The differences decreased from an average overestimation of  $-2.7$  hours per day at T1 to an overestimation of only  $-0.7$  hours per day (Table 4). This clearly shows that patients are able to estimate their wear time better the more often they get to know their actual wear times. Using wear-time recording it is possible to objectify the patient's adherence and thus it could be possible to explain stagnation and failures in treatment.<sup>1</sup>

The objective wear times in the study group were slightly higher at T3 but showed no significant difference. At T4 the mean wear time returned to the initial value of 8.1 hours per day in the study group. In the control group a steady increase of wear time from 6.7 hours per day to 8.1 hours per day was found. Objective wear times recorded at T4 were very similar in both groups, which may lead to the conclusion that in long term the wear time approximates these values.

Surprisingly, significant differences regarding wear times between the study and the control group could not be found for mean wear time during the whole study or for each appointment. This could be a consequence of the thorough education and motivation performed in both groups before the removable appliance was inserted. Findings in the literature that patients aware of the wear-time recording wear their appliances significantly more often than patients unaware of this fact<sup>12</sup> could not be supported by this study.

In the literature, there is no uniformity concerning the influence of gender on wear time. Significant differences between girls and boys are mentioned<sup>7</sup> but no influence of sex has also been assumed.<sup>8</sup> Our findings support the latter because no significant differences regarding overall wear time among genders could be found in the study group.

The mean age of the study group appeared to be 3 years more than the mean age of the control group. Some studies conclude that patients age 12 years or younger show higher levels of compliance,<sup>19,20</sup> while

**Table 4.** Overview of the Subjective and Objective Wear Times (Hours per Day) and Their Differences in the Study Group for Each Appointment (T1, T2, T3, T4); Significant Values ( $P < .05$ ) Appear in Italics

| Wear Time            | T1                 | T2                 | T3                 | T4                 |
|----------------------|--------------------|--------------------|--------------------|--------------------|
| Subjective wear time | 10.8 ( $\pm 2.3$ ) | 9.2 ( $\pm 2.5$ )  | 9.1 ( $\pm 2.5$ )  | 8.8 ( $\pm 2.0$ )  |
| Objective wear time  | 8.1 ( $\pm 3.1$ )  | 8.4 ( $\pm 2.8$ )  | 8.2 ( $\pm 2.4$ )  | 8.1 ( $\pm 2.2$ )  |
| Difference           | -2.7 ( $\pm 2.9$ ) | -0.8 ( $\pm 2.5$ ) | -0.9 ( $\pm 2.5$ ) | -0.7 ( $\pm 2.4$ ) |
| <i>P</i>             | .001               | .267               | .184               | .711               |

others have found no correlation between the patient's age and the level of compliance.<sup>21,22</sup>

Our data are also in accordance with the results presented by Kacer et al.<sup>8</sup> that the type of appliance does not influence the levels of adherence. A decisive factor could be a similar willingness of the patient to achieve and retain an acceptable result.

Our clinical impression could not support the worries mentioned in literature.<sup>1,4</sup> The patients and parents showed very few reservations about wear-time recording, and in most cases were extremely interested in the measured wear times.

## CONCLUSIONS

- It could be shown that patients tend to overestimate their wear time by approximately one-third when they do not know that wear time is recorded. The first subjective assessment differed significantly from all others. The longer patients were confronted with their objective wear times, the more accurate their subjective estimations became.
- No significant differences regarding wear time between the different appointments and total mean wear time could be found for the study group or the control group. Likewise, no significant differences among genders and type of removable appliance regarding overall wear time were found.
- This study shows that recording wear time and informing patients about this fact can lead to a better subjective estimation of wear time by the patient and can add to more transparency regarding the patient's compliance and thus to a better understanding of possible stagnation or failures in treatment.
- Knowing that wear time is recorded does not necessarily increase the amount of time removable appliances are worn by a patient.

**Table 5.** Comparison of Differences Between Subjective and Objective Wear Time at Each Appointment (T1, T2, T3, T4) to All Others of the Study Group; Significant Values ( $P < .05$ ) Appear in Italics

|    | T1   | T2   | T3   | T4 |
|----|------|------|------|----|
| T1 |      |      |      |    |
| T2 | .012 |      |      |    |
| T3 | .038 | .586 |      |    |
| T4 | .048 | .845 | .845 |    |

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